IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO ALL WAVE 2 CASES

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF TIMOTHY MCKINNEY, M.D.

This Memorandum applies to all Wave 2 cases as identified in **Exhibit A**, attached to Plaintiffs' accompanying Motion. Plaintiffs also hereby adopt and incorporate by reference the *Daubert* motion filed with respect to Timothy McKinney, M.D. in Wave 1, [Dkt. 2001 (motion), 2002 (memorandum in support)], related to his opinions on Defendants' Gynemesh PS and respectfully request the Court exclude his testimony for the reasons expressed in the Wave 1 briefing. Pursuant to Federal Rule of Evidence 702, Plaintiffs hereby seek to further limit certain opinions and testimony proffered by Defendant Johnson & Johnson and Ethicon, Inc.'s (hereinafter "Defendants") expert Timothy McKinney, M.D. on their TVT and TVT-O products. In support of their Motion, Plaintiffs respectfully show the Court as follows:

I. INTRODUCTION

Timothy McKinney, M.D. ("Dr. McKinney") is a diplomate of the American Board of OB/GYN and is board certified in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery.[1] However, Dr. McKinney offers opinions in these cases that are beyond

[1] *See Expert Report of Timothy McKinney, MD on TVT* attached to Plaintiffs' Motion to Limit the Opinions and Testimony of Timothy McKinney (hereinafter the "Motion") as **Exhibit B**; *see*

his field of expertise, not supported by reliable methodology, or not supported by reliable application of methodology. Dr. McKinney has proffered an expert report on Defendants' TVT and TVT-O products. *See generally* Ex. A. Dr. McKinney opines that Defendants' products are safe; that voluminous medical literature supports the safety of Defendants' products; that Defendants' products do not suffer from undisclosed defects; and that all pelvic floor surgeons would be aware of any risks associated with using Defendants' products. In arriving at these conclusions, Dr. McKinney sets forth opinions that are: (a) irrelevant or prejudicial in that they may confuse or mislead the jury; (b) speculative and unsupported by the medical literature or his experience; or (c) outside of Dr. McKinney's area of expertise.

As such, Dr. McKinney offers these opinions despite lacking specialized knowledge of these topics, without utilizing a proper methodology, or without reliably applying methodology as required by Federal Rule of Evidence 702. All of Dr. McKinney's opinions and testimony suffering from these defects should be excluded or limited.

II. LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403, and 104. *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony). The trial judge acts as a gatekeeper for scientific, technical, and other specialized knowledge. *See Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579, 588 (1993); *Kumho Tire Co., v. Carmichael*, 526 U.S. 137, 141 (1999).

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also Curriculum Vitae: Timothy Brian McKinney, M.D., attached to Plaintiffs' Motion as **Exhibit C**.

III. ARGUMENT

Dr. McKinney's medical training in the fields of obstetrics and gynecology do not automatically render his opinions on other ancillary issues admissible. *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001. Indeed, each individual opinion he offers must satisfy the requirements of the Federal Rules of Evidence to be admissible. *See, e.g.*, *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997)

As a threshold matter, an expert witness "must have 'knowledge, skill, experience, training, or education' in the subject area in which he will testify." *Bombardiere v. Schlumberger Tech. Corp.*, 934 F. Supp. 2d 843, 846 (N.D. W. Va. 2013 (quoting Fed. R. Evid. 702). In the context of Rule 702 knowledge "connotes more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the *matters upon which she will opine are clearly within her area of expertise*." *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D.N.C. 2007 (emphasis added). Thus, a fundamental prerequisite to admission of an expert's opinion is that the opinion be related to that expert's specialized knowledge. *See, e.g.*, *U.S. v. Johnson*, 54 F.3d 1150, 1157 (4th Cir. 1995. Under this clear standard, Dr. McKinney, just like any other expert witness, may only testify on subjects within his area of expertise.

Additionally, Dr. McKinney's opinions must be based upon reliable and proper methods. *See Coleman v. Union Carbide Corp.*, 2013 WL 5461855, at *17 (S.D. W. Va. 2013) (holding that expert testimony must be reliable and relevant to be admissible). As this Court has recognized in a related MDL:

> Just because an expert may be "qualified . . . by knowledge, skill, experience, training or education" does not necessarily mean that the opinion that the expert offers is "the product of reliable principles and methods" or that the expert "has reliably applied the principles and methods to the facts of the case."

Cisson v. C.R. Bard, Inc., 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013). The burden is on the Defendant to show that *each* of Dr. McKinney's opinions has a reliable foundation based on stated principles and methods. *See Daubert*, 509 U.S. at 597. Opinions which are not within Dr. McKinney's area of expertise, which are not the product of reliable principles and methods, or which are not the product of reliable application of principles and methods should be excluded.

A. All Irrelevant or Prejudicial Opinions Proffered by Dr. McKinney Should be Excluded.

As with any other form of proffered evidence, expert testimony must be relevant to be admissible. *Coleman*, 2013 WL 5461855, at *17. Here, Dr. McKinney seeks to opine on a variety of irrelevant or improperly prejudicial issues, including: (1) that "[n]ative tissue *prolapse* repairs have high rates of recurrence;" (2) the adverse event rates reported in the SISTEr trial, which did not utilize synthetic midurethral slings at all, let alone Defendants' products; (3) a 2015 Cochrane review focused on the *procedure* by which midurethral slings are implanted, not safety, to support his opinion that Defendants' products are safe; (4) the "Nilsson" study as support for his opinion that Defendants' products are safe in spite of the fact that the Nilsson study looked at patients implanted with synthetic slings in Europe *prior* to Defendants introduction of TVT to the market in the United States and using a different *methodology* for implantation than that used in the United States; (5) that Plaintiffs' experts rely on "the lowest level of evidence" without citing to such evidence; (6) that TVT and TVT-O are the "gold standard;" and (7) that use of the TVT and TVT-O "represent an escape from the dark- ages [sic]." Ex. B at 4, 10, 14, 17-18, 19-21, 25, 32 (emphases added). These irrelevant or prejudicial opinions should be excluded.

1. Dr. McKinney Should Not be Permitted to Opine on Native Tissue Prolapse Repairs.

Dr. McKinney opines: "Native tissue *prolapse* repairs have high rates of recurrence." Ex. B at 4 (emphasis added). However, Dr. McKinney's expert report is limited to Defendants' TVT and TVT-O products. *See generally* Ex. B; *see also Deposition of Timothy B. McKinney, M.D.* dated June 29, 2016, attached to Plaintiffs' Motion as **Exhibit D**, at 8:23-9:2. TVT and TVT-O are used to treat stress urinary incontinence ("SUI"), not prolapse. Ex. B at 6 (noting TVT and TVT-O are surgical options used in treating SUI). Given that Dr. McKinney's expert report in this matter is limited to his opinions regarding TVT and TVT-O, both of which are products used to treat SUI, any opinions on "prolapse" repairs, especially prolapse procedures using native tissues, *i.e.*, procedures that involve none of Defendants' mesh products let alone synthetic SUI products, are irrelevant and should be excluded.

2. Dr. McKinney Should Not be Permitted to Opine on the Adverse Events Reported in the SISTEr Trial.

Dr. McKinney opines: "For example, as discussed later in the SISTEr trial that was conducted by the Urinary Incontinence Network, 47% of the *Burch* patients and 63% of the *fascial* sling patients had adverse events." Ex. B at 14 (emphases added). Dr. McKinney further explains the results of the SISTEr study in some detail, noting that the Burch and fascial sling procedures use "autologous rectus fascia," *i.e.*, these procedures use natural tissue not synthetic sling material. Ex. B at 17. Thus, any adverse events as related to the two procedures examined in the SISTEr trial are simply not relevant to the safety or efficacy of Defendants' TVT or TVT-O products as Defendants' products utilize synthetic material.

Moreover, because Dr. McKinney holds the opinion that all procedures to correct SUI prior to the introduction of TVT and TVT-O existed during the "dark ages," Ex. B at 32, and that

he was "relieved when TVT, TVT-O, [and] retropubic slings from all companies came about," Ex. D at 164:10-12, there exists the real possibility that his opinions in this regard will confuse the jury insofar as they may infer, consistent with Dr. McKinney's implication, that high adverse event rates with prior non-synthetic procedures logically lead to the assumption that Defendants' TVT and TVT-O products are safe. This conclusion does not follow as prior non-synthetic procedures may have had high incidents of adverse events (although Plaintiffs do not concede this fact) and Defendants' current products may still be unsafe. As the two propositions are not mutually exclusive and Dr. McKinney's expert report impermissibly conflates the two, these opinions should be excluded.

3. Dr. McKinney Should Not be Permitted to Opine on the 2015 Cochrane Review.

Dr. McKinney relies heavily on the 2015 Cochrane Review calling it one of the "highest levels of evidence," for his opinions that Defendants' products have a "good safety profile." Ex. B at 19-20. Additionally, Dr. McKinney states: "the Ford 2015 Cochrane Review included 81 trials that evaluated 12,113 women the *majority of which concerned the TVT and TVT-O devices*." Id. (emphasis added). Dr. McKinney's opinions strain the relevance of the scope and results of the 2015 Cochrane review and are grossly misleading. First, the 2015 Cochrane Review expressly noted: "Most of our results are based on moderate quality evidence. Most trials did not describe their methods clearly, thus leading to some degree of uncertainty in the findings. At present there are only a limited number of randomized controlled trials . . . This means that evidence about how effective and safe these procedures are in the longer term lags behind the

evidence for them in the short and medium term (up to five years)."[2] Therefore, Dr. McKinney's statement that 2015 Cochrane Review is one of the "highest levels of evidence" is misleading as the Review is premised upon "moderate" evidence. This opinion should be excluded.

More importantly, the 2015 Cochrane Review "looked at the effects of mid-urethral sling operations when these two different *methods* [retropubic or transobturator] of performing the operations were used . . . The purpose of the review was to find out how effective these operations are in the treatment of stress urinary incontinence and to help determine the rate of potential complications or problems." Ex. E at 4 (emphasis added). Thus, the primary purpose of the 2015 Cochrane Review was to compare surgical methods, not products. Additionally, Dr. McKinney provides no basis for his opinion that "the Ford 2015 Cochrane Review included 81 trials that evaluated 12,113 women the *majority of which concerned the TVT and TVT-O devices*," and as such, his basis for using the 2015 Cochrane Review for his opinion that Defendants' specific products are safe is fundamentally flawed. Even if it was possible to segregate the TVT and TVT-O related data from the entire data set contained within the 2015 Cochrane Review, Dr. McKinney did not do so, and therefore, cannot draw any relevant conclusions in this regard.

With respect to long-term safety outcomes, the 2015 Cochrane Review cautions: "We encourage researchers to publish longer-term data to help increase the reliability of longer-term results in this area." Ex. E at 4. Dr. McKinney is attempting to shoehorn the results of the 2015 Cochrane Review into forming a basis for his opinion that Defendants' products have a "good

[2] **Exhibit E** at 4, Ford AA, et al., Mid-urethral sling operations for stress urinary incontinence in women (Review), Cochrane Database of Systematic Reviews, Issue 7 Art. No.: CD006375 (2015), attached to Plaintiffs' Motion.

safety profile" even though the results do not expressly or implicitly support this opinion, and as such, these opinions should be excluded.

4. Dr. McKinney Should Not be Permitted to Opine on the Nilsson Study.

Dr. McKinney's reliance on the Nilsson study in support of his opinion that Defendants' products are safe is similarly problematic. Dr. McKinney's opinion is straightforward: "The Nilsson 17 year study of the TVT mesh demonstrated excellent efficacy over the long term and very low complications." Ex. B at 24. Dr. McKinney's deposition testimony undermines this conclusion:

> Q. Okay. And for TVT, in fact, the -- when the TVT was brought over to the United States, the cohort that had the 17-year experience was done in Europe, correct?
>
> A. Nilsson.
>
> Q. And, in fact, the procedure or the implant technique that was used on those folks was actually different than the implant technique used in the United States, correct?
>
> A. Not -- it all depends.
>
> Q. Well, the -- let me ask you this: The original implant technique in Europe was done with the patients awake, correct?
>
> A. A lot of them.
>
> Q. And --
>
> A. Some were even done with spinal anesthesia, so that's --
>
> Q. Well, that's -- that was going to be my next question.
>
> A. Yeah.
> . . .
>
> Q. So, Doctor, would you disagree with me that that original procedure is different than the procedure that's in the TVT IFU that was brought over into the United States?

A. Not necessarily….

Ex. D at 177:2-24; 179:22-180:3. The Nilsson study was conducted in Europe before Defendants' products were introduced in the United States and followed a group of individuals that was implanted with Defendants' products utilizing a different procedure than that marketed by Defendants in the United States. It is not even clear that the products were made with the same materials. Therefore, Dr. McKinney's reliance on the Nilsson study to support his safety and efficacy opinions on Defendants' products is inherently flawed, unreliable, and should be excluded.

5. Dr. McKinney Should Not be Permitted to Testify that Plaintiffs' experts rely on "the lowest level of evidence."

Dr. McKinney's opinion that Plaintiffs' experts rely on "the lowest level of evidence" is completely unsupported in his expert report. Ex. B at 10. Expressing this opinion without, at the very least, pointing to the evidence Dr. McKinney believes to be "the lowest level of evidence," constitutes an improperly prejudicial opinion with no basis, and therefore, should be excluded.

6. Dr. McKinney Should Not be Permitted to Testify that TVT and TVT-O are the "Gold Standard."

Dr. McKinney opines that: "The TVT and TVT-O are the Gold Standard and standard of care for treating stress urinary incontinence." Ex. B at 7. First, this ascription of "Gold Standard" status to Defendants' products is not accompanied with any basis for the conclusion. An opinion with no basis is conjecture or speculation and should be excluded on that basis alone. Second, the term "Gold Standard" implies various traits about Defendants' products, not the least of which is that Defendants' products are the first choice for surgeons when treating SUI. This implication runs the serious risk of confusing and misleading the jury in that the jury may discount other surgical procedures proffered by Plaintiffs as safer alternatives. After all, why would any patient

or physician forego a treatment option when an expert states that option is the "Gold Standard?" This misleading and unsupported opinion is exactly the type of unreliable evidence that is proper for exclusion under *Daubert*.

7. Dr. McKinney Should Not be Permitted to Testify that Use of the TVT and TVT-O "Represent an Escape from the Dark Ages."

Dr. McKinney's opinion that the introduction of TVT and TVT-O "represent an escape from the dark ages," Ex. B at 32, is clearly improperly prejudicial in that it implies that Defendants single handedly brought women's health out of an era marked by the bubonic plague, the Inquisition, and intellectual suppression, among other ills. Dr. McKinney's analogy is hardly apt nor is it fair; however, it is misleading and confusing. For these reasons, Dr. McKinney should be excluded from expressing this opinion.

B. All Speculative Opinions, Unsupported by the Medical Literature or Dr. McKinney's Experience, Should be Excluded.

Dr. McKinney expresses numerous speculative opinions, with no stated basis in the medical literature or his experience, and these opinions are properly excluded under a *Daubert* analysis. *See also Horton v. W. T. Grant Co.*, 537 F.2d 1215, 1218 (4th Cir. 1976) (relevant testimony may be received if and only if the expert is in possession of such facts as would enable him to express a reasonably accurate conclusion as distinguished from mere conjecture). Dr. McKinney's speculative opinions include: (1) "The frustration to all of us is that native tissue, which in this population of patients is inherently poor, had an unacceptable failure rate," Ex. B at 4; (2) "Surgery for stress urinary incontinence has been shown to be the most definitive treatment," Ex. B at 5; (3) "Of all the sling procedures, the Type 1 macroporous, monofilament, polypropylene mesh used in the TVT and TVT-O has the longest and broadest track record of safe and effective use." Ex. B at 11; (4) "The pore size for the TVT and TVT-O mesh is

macroporous (> 75 microns) . . . . ," Ex. B at 13; and (5) "SUI surgery, including the TVT and TVT-O are taught at many residencies and fellowship programs in the United States and Texas specifically," Ex. B at 16.

First, there is no way for Dr. McKinney to what the "frustration[s]" of all surgeons were, or are, nor does Dr. McKinney attempt to explain how he possesses this knowledge. Therefore, this opinion should be excluded. Second, Dr. McKinney's opinion that surgery for SUI has been shown to be the "most definitive treatment" is not only vague and ambiguous as it is unclear what the statement actually means, but it is also proffered without support and should be excluded. Third, Dr. McKinney's opinion that TVT and TVT-O have the "longest and broadest track record of safe and effective use" only finds a basis if his misinterpretations of the SISTEr Trial, 2015 Cochrane Review, and the Nilsson study are permitted into evidence for their proffered purposes. However, as described above, Dr. McKinney's use of those studies is fundamentally flawed, and as such, the instant opinion on TVT and TVT-O's "safe and effective use" should be excluded.

Fourth, Dr. McKinney opines that the pore size for the TVT and TVT-O mesh is "macroporous." However, Dr. McKinney provides no basis for this opinion in his report and explained why in deposition:

> Q. Now, Doctor, in preparing your report here, did you do a literature search specific to pore size to opine what the appropriate pore size for vaginal mesh should be?
>
> A. I did not find anything, no.
>
> Q. You did not find anything. Did you actually go about and do a search for material specific to vaginal mesh pore size?
>
> A. I did not.

Ex. D at 34:15-35:1. As such, it is clearly evident that Dr. McKinney's opinion on pore size, specifically whether the mesh in Defendants' TVT and TVT-O are "macroporous," is unsupported speculation and should be excluded. Finally, Dr. McKinney provides no basis for his opinion that TVT and TVT-O procedures are taught in residencies and fellowships across the nation, specifically Texas. A review of Dr. McKinney's curriculum vitae reveals that he is not licensed in Texas nor does he appear to have ever taught in any setting in Texas. *See generally* Ex. C. Additionally there does not appear to be any basis for how Dr. McKinney is aware that this practice occurs nationwide nor is there an explanation for why residencies and fellowships nationwide would choose to use only Defendants' products. For these reasons, this speculative opinion should also be excluded.

C. All Opinions Outside of Dr. McKinney's Expertise Should be Excluded.

Dr. McKinney stated in deposition that he may offer opinions not expressed in his expert report and which are outside his area of expertise. Any opinion not expressed in his expert report should be excluded on that basis alone. Fed. R. Civ. P. 26(a)(2)(B)(i) (a testifying expert must provide a written report containing a complete statement of all opinions the witness will express and the basis and reasons for them). Even if the Court determines that disclosure of additional opinions in deposition is sufficient under the Federal Rules of Civil Procedure, Dr. McKinney's previously undisclosed opinions lie in areas in which he is not an expert. Specifically, in deposition, Dr. McKinney indicated he may opine on: (1) the Section 510(k) process; and (2) the adequacy of Defendants' IFUs.

1. Dr. McKinney is Not Qualified to Opine on the Section 510(k) Process.

In deposition, Dr. McKinney testified:

> Q. Okay. Are you going to be offering opinions relative to the 510(k) process versus a premarket approval.

> A. Not heavily, no.
>
> . . .
>
> Q. And they were not approved [referring to 510(k) process] for safety and efficacy -- proven safety and efficacy before this, were they?
>
> A. It was my thought process that the 510(k) would have been sufficient for use in surgery, and therefore, it was approved that way.

Ex. D at 29:18-21; 108:22-109:4. Dr. McKinney testified in deposition that he would not testify "heavily" regarding the Section 510(k) process leaving open the possibility he may opine on this process to some extent. Apart from admitting he his not a regulatory expert, Ex. D at 29:11-14, it is clear that Dr. McKinney fundamentally misunderstands the Section 510(k) process when he testified that the Section 510(k) process would have "approved" a product for safety and efficacy.

A wealth of authority holds that the Section 510(k) process is not related to product safety or efficacy, as well as abundant case law holding that there are no safety requirements imposed by way of the Section 510(k) process.[3] The FDA itself explained the difference between the Section 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004) ("A pre-market notification submitted under 510(k) is thus entirely different from a [premarket approval,] which must include data sufficient to demonstrate that the device is safe and effective").

[3] *See, e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) ("[D]evices that enter the market through § 510(k) have 'never been formally reviewed under the MDA for safety or efficacy"); *Smith v. Depuy Orthopaedics, Inc.*, 2013 WL 1108555, at *4 (D.N.J.2013) ("The 510(k) process is different from PMA because under the 510(k) process, the FDA must find that a new device is ''substantially equivalent' to another device exempt from premarket approval' instead of making a determination regarding the safety and effectiveness of the device….The device is not 'formally reviewed ... for safety or efficacy.'").

Dr. McKinney's clear misunderstanding of the 510(k) process falls short of the "specialized knowledge" required by Rule 702. Because Dr. McKinney is not an expert on FDA regulations, he should be prevented from testifying as to the significance of the Section 510(k) approval of the TVT and TVT-O devices.

2. Dr. McKinney is Not Qualified to Opine the Adequacy of Defendants' IFUs.

Dr. McKinney testified in deposition:

> Q. You mentioned that the basic premise was that in an IFU, it's your opinion that not all risks should be shown, but the unique risks of a device should be known -- should be stated in the IFU; is that right?
>
> A. Yes.
> . . .
>
> Q. And so you would agree that when material is in an IFU, which would be -- in terms of contraindications, a doctor should be able to rely on that?
>
> A. They should be able to read it and understand a general concept of what can potentially happen.

Ex. D at 171:22-172:4; 176:15-21. Dr. McKinney's opinions on Defendants' IFUs are directly related to the adequacy of these IFUs. Dr. McKinney proffers these opinions despite the fact that he is not an expert in drafting IFUs or on what warnings should be provided. Ex. D at 32:7-15.[4] As such, Dr. McKinney's opinions related to the adequacy of Defendants' IFUs should be excluded. *See also Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013) (wherein this Court, in similar litigation, previously recognized that a doctor unfamiliar with federal regulations regarding IFUs is unqualified to testify about the adequacy of warnings).

[4] Dr. McKinney did testify that he invented a diagnostic device of some sort; however, he indicated that he worked on drafting the IFU for that product with a "regulatory department." Ex. D at 156:19-157:13. Dr. McKinney does not profess to have expertise in this area or familiarity with the federal regulations that govern this area.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request Dr. McKinney's opinions that are: (a) irrelevant or prejudicial in that they may confuse or mislead the jury; (b) speculative and unsupported by the medical literature or his experience; or (c) outside of Dr. McKinney's area of expertise be excluded.

Specifically, Dr. McKinney should be prevented from opining on a variety of irrelevant or improperly prejudicial issues, including: (1) that "[n]ative tissue *prolapse* repairs have high rates of recurrence;" (2) the adverse event rates reported in the SISTEr trial, which did not utilize synthetic midurethral slings at all, let alone Defendants' products; (3) a 2015 Cochrane review focused on the *procedure* by which midurethral slings are implanted, not safety, to support his opinion that Defendants' products are safe; (4) the "Nilsson" study as support for his opinion that Defendants' products are safe in spite of the fact that the Nilsson study looked at patients implanted with synthetic slings in Europe *prior* to Defendants introduction of TVT to the market in the United States and using a different *methodology* for implantation than that used in the United States; (5) that Plaintiffs' experts rely on "the lowest level of evidence" without citing to such evidence; (6) that TVT and TVT-O are the "gold standard;" and (7) that use of the TVT and TVT-O "represent an escape from the dark- ages [sic]."

Dr. McKinney should also be prevented from providing speculative opinions including: (1) "The frustration to all of us is that native tissue, which in this population of patients is inherently poor, had an unacceptable failure rate;" (2) "Surgery for stress urinary incontinence has been shown to be the most definitive treatment;" (3) "Of all the sling procedures, the Type 1 macroporous, monofilament, polypropylene mesh used in the TVT and TVT-O has the longest and broadest track record of safe and effective use;" (4) "The pore size for the TVT and TVT-O

mesh is macroporous (> 75 microns) . . . ;" and (5) "SUI surgery, including the TVT and TVT-O are taught at many residencies and fellowship programs in the United States and Texas specifically."

Finally, Dr. McKinney should be prevented from presenting any undisclosed opinions outside of his area of expertise, including opinions on: (1) the Section 510(k) process; and (2) the adequacy of Defendants' IFUs.

Dated: July 21, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2016, a true and correct copy of **PLAINTIFFS' MOTION AND MEMORANDUM IN SUPPORT TO LIMIT THE OPINIONS AND TESTIMONY OF TIMOTHY MCKINNEY, M.D**. was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

Dated: July 21, 2016

Respectfully submitted,

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